

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: Ethicon Wave 1 cases listed in Exhibit A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO EXCLUDE
CERTAIN OPINIONS AND TESTIMONY OF BARRY SCHLAFSTEIN, M.D.**

Plaintiffs state as follows in support of their motion seeking to preclude defense expert Barry Schlafstein, M.D., a urogynecologist, from giving opinions on (1) the design of Defendants' transvaginal mesh products at issue, including the safety and efficacy of those devices; (2) his statements about the safety and efficacy of Defendants' products based on his own practice; and (3) the adequacy of Defendants' product warnings and instructions for use ("IFU").

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, “the district court must decide whether the expert has ‘sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.’” *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents “scientific knowledge,” meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury—i.e., whether it is relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert’s opinions “fit” the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

To meet the standard of reliability, the testimony “must be supported by appropriate validation—i.e., ‘good grounds,’ based on what is known. In short, the requirement that an expert’s testimony pertain to ‘scientific knowledge’ establishes a standard of evidentiary reliability.” *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995).

There are five factors courts often consider, taken from the *Daubert* opinion, in assessing the reliability of expert testimony:

- (1) whether the testimony has been tested,
- (2) whether it has been published or exposed to peer review,
- (3) its rate of error,
- (4) whether there are standards and controls over its implementation, and
- (5) whether it is generally accepted.

See Cavallo v. Star Enterprise, 100 F.3d 1150, 1158 (4th Cir. 1996). However, “the factors discussed in *Daubert* were neither definitive, nor exhaustive.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

Courts should focus on expert witnesses’ “principles and methodology, not on the conclusions that they generate.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). This is because “*Daubert* governs whether evidence is admitted, not how persuasive it must be to the factfinder.” *Cavallo*, 100 F.3d at 1158.

ARGUMENT

This Court should prohibit Dr. Schlafstein from giving the opinions referenced above because he is not qualified to opine on those issues and has not done the necessary research to produce opinions that can reliably be applied to this case.

Dr. Schlafstein has issued two lengthy reports, one addressing the TVT-O, and one addressing both the Prolift and Prolift + M products (collectively, the “subject products”). All of these reports contain the same general opinions/statements:

- The subject products are not defective, were reasonably safe for their intended use, and had a positive benefit-to-risk profile. The benefits of the subject products outweigh the risks of using the products, and they are safer and better than the non-mesh alternatives. The products at issue could not have been made safer for their

intended uses at the time they were launched, and the products were state of the art at the time they were launched. (See TVT-O Report, attached as Exhibit B, at 8, 11; Prolift and Prolift + M Report, attached as Exhibit C, at 3, 12).

- Various statements about Dr. Schlafstein's experience in his own practice related to the safety and efficacy of Defendants' products at issue. (See TVT-O Report, Ex. B, at 4, 9; Prolift and Prolift + M Report, Ex. C, at 3, 10).
- The IFU and/or the warnings concerning the subject products are adequate and allow for the safe use of the device. (See TVT-O Report, Ex. B, at 8; Prolift and Prolift + M Report, Ex. C, at 8).

The first bullet point does not use the word "design," but it clearly is an opinion about the subject products' design. That opinion recites the legal test on a design defect claim in West Virginia. See *Morningstar v. Black & Decker Mfg. Co.*, 253 S.E.2d 666, 683 (W. Va. 1979) (stating that "the general test for establishing strict liability in tort is whether the involved product is defective in the sense that it is not reasonably safe for its intended use"). Additionally, it addresses the risk-utility test, which is part of the inquiry into a design defect claim in numerous states. See, e.g., *Beard v. Johnson & Johnson, Inc.*, 41 A.3d 823, 836 (Pa. 2012); *Branham v. Ford Motor Co.*, 701 S.E.2d 5, 14 (S.C. 2010); *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 352 (Ill. 2008), *opinion modified on denial of reh'g* (Dec. 18, 2008); *Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 258 (Tex. 1999); *Halliday v. Sturm, Ruger & Co.*, 792 A.2d 1145, 1150 (Md. Ct. App. 2002); *Cavanaugh v. Skil Corp.*, 751 A.2d 564, 580 (N.J. Super. App. Div. 1999), *aff'd*, 751 A.2d 518 (N.J. 2000). The next point addresses the possibility of alternative designs, which generally factor into the design defect analysis in some manner. See, e.g., *Branham*, 701 S.E.2d at 14; *Hernandez*, 2 S.W.3d at 258; *Halliday*, 792 A.2d at 1150.

For the reasons described below, Dr. Schlafstein should not be permitted to give those opinions under the standards set by Rule 702 and *Daubert*.

I. Dr. Schlafstein should be precluded from giving design opinions.

a. Dr. Schlafstein expressly testified he is not a design expert.

The first reason, and perhaps the most important reason, that Dr. Schlafstein should be precluded from opining about the design of the subject products is that he admits he is not an expert on design:

Q. Do you consider yourself to be an expert on the design of transvaginal mesh?

A. More on the use, not the design.

Q. I think we established you've never designed a medical device yourself that was taken to market; correct?

A. That is correct.

(April 4, 2016 Deposition of Barry Schlafstein, M.D. ("Schlafstein Deposition"), portions attached as Exhibit D, at 213:6-12).

Q. Do you know what standards a manufacturer must follow in designing mesh products?

A. I think it's between them and the – whoever the regulatory agencies are, so, no.

Q. You wouldn't have any expertise in that; correct?

A. Not in the manufacturing, no.

(*Id.* at 212:9-15).

This Court has previously recognized the importance of an expert's admission that he is not an expert. In the *Bard* litigation, this Court precluded Dr. Shull from giving warnings opinions because he had testified that "I would not claim to be an expert in that area." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), *amended on reconsideration in part*

(June 14, 2013). That same analysis applies here to Dr. Schlafstein, who admitted on multiple occasions during his recent deposition that he is not an expert on design. As such, he should be precluded from giving any opinions related to design of the subject products.

b. Dr. Schlafstein did not review Defendants' key documents related to product design, and even if he had reviewed them Dr. Schlafstein has no base of knowledge as to what those documents would demonstrate.

Dr. Schlafstein should also be precluded from opining about the design of the subject products because he has not reviewed Defendants' internal documents about the design process. In the Boston Scientific litigation, Boston Scientific Corp. ("BSC") moved to exclude Dr. Shull because he "reached opinions on the improper design of the Uphold without having first considered BSC's design protocols." *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015). The plaintiffs countered that Dr. Shull had relied on other BSC internal documents, as well as the scientific literature. *Id.*

This Court agreed with BSC and excluded Dr. Shull from giving any design opinions. This Court reasoned that "regardless of the literature he has reviewed or the experience he has gained, a necessary piece of data remains missing from Dr. Shull's methodology. Without any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were (1) departures from the norm; (2) not followed by BSC; or (3) lacking in any way." *Id.*

Similarly, Dr. Schlafstein should be excluded in part due to his failure to even consider these important design documents. He confirmed repeatedly that he did not review Defendants' internal operating procedures or any other internal design documents in formulating his opinions:

Q. Have you ever reviewed any of Ethicon's internal standard operating procedures?

A. No.

(Schlafstein Deposition, Ex. D, at 212:16-18).

Q. Did you read every document that is on your reliance list?

A. I did not read every single document that's on this reliance list, no.

Q. For instance, if you go to, they're not numbered, but the third or fourth from last page, do you see at the bottom there are several documents with a convention code that says "ETH.MESH" and then "." numbers? Do you see that?

A. Yes.

Q. Is it fair to say that you didn't request those documents?

A. That is fair to say.

Q. Is it fair to say that you didn't review those documents?

A. That is fair to say.

Q. Similarly, if there are some internal documents that are listed on this reliance list, based upon your testimony previously, it's fair to say that those weren't things that you read and considered in your expert report; right?

A. And just to be clear, by "internal," you're referring to?

Q. Documents, e-mails, things that were only between Ethicon employees.

A. The answer then would be correct.

Q. You did not review those?

A. Correct.

Q. And you did not consider them in forming your opinions; correct?

A. Correct.

(Schlafstein Deposition, Ex. D, at 149:10 – 150:17). Because he did not review the relevant design documents, Dr. Schlafstein lacks the required knowledge to give a reliable opinion about the design of Defendants' transvaginal mesh products.

Based on the foregoing, Dr. Schlafstein's opinions on the issue of product design should be excluded.

II. Dr. Schlafstein's statements about his personal experience related to the safety and efficacy of the subject products should be excluded because he has kept no records on those points, so any such opinions are not reliable.

Dr. Schlafstein should be precluded from testifying about his perceived safety and efficacy rates with the subject product from his own practice, as that information exists only in Dr. Schlafstein's head and is entirely unsupported by any statistical information/analysis. As an example, Dr. Schlafstein's Prolift and Prolift + M report includes the following statement:

I have performed more than 630 trans-vaginal mesh augmented colporrhaphy procedures. In treating POP for many years, I have implanted various manufacturers' synthetic mesh products, including Gynemesh PS, Prolift, and Prolift+M. I am familiar with the substantial body of peer-reviewed published medical literature regarding Pro lift mesh products, (including Gynemesh PS, Prolift, and Prolift+M) which demonstrate the safety and efficacy of these products and on which I rely for my opinions that these products are safe and effective for treating POP. My preferred choice for treating SUI has been and continues to be Ethicon's TVT-O, TVT-Abbrevio, and TVT-Exact inasmuch as I believe them to be safe and effective products for surgically treating this condition. I am familiar with the TVT-R product as well and the substantial body of peer-reviewed published literature regarding the TVT products which demonstrate that these products are safe and effective in treating SUI I have implanted more than 950 TVT products listed above.

(Schlafstein Prolift and Prolift + M Report, Ex. C, at 3).

The report continues on to say:

In the appropriately screened and selected patient, after a verbal and visual explanation of the procedure, and after appropriate informed consent, I will offer treatment with a mesh augmented colporrhaphy. Wherever possible we have maintained close ongoing surveillance of such patients after their mesh-augmented colporrhaphy procedure. Although as yet unpublished, our outcomes to date, have been favorable. The overwhelming majority of such patients have expressed extreme satisfaction with their experience, and not infrequently the results have been enthusiastically described as 'life-changing.'

(*Id.* at 10).

Defendants have now caught on to the fact that their experts' opinions about complications rates among their own patients are inappropriate, unsupported and inadmissible, so Dr. Schlafstein now seeks to backdoor essentially the same opinion by excluding a precise complication rate. This should not be permitted, as Dr. Schlafstein lacks any data or analysis to support his conclusions:

A. Well, I don't have the number of Prolift or Prolift+M. I have the number of transvaginal mesh procedures, which would include Prolift and Prolift+M, and it would include other types of meshes. So that would be -- that number, which would include all the transvaginal meshes, would be greater than 630 transvaginal procedures. Transvaginal mesh procedures.

Q. Greater than, did you say, 600?

A. 6-3-0.

Q. 6-3-0. Do you have any way to quantify, of those 630 procedures, approximately how many would have been Ethicon products versus other manufacturers?

A. No, I'd have to go back. I'd have to do a little more detailed analysis, which would be the date -- you know, looking at the dates of the procedures and before and after.

(Schlafstein Deposition, Ex. D, at 109:11- 110:4).

Q. And I believe, based upon your answer earlier, the only way to do that would be a chart search; is that correct?

A. That is correct.

(*Id.* at 110:17-20).

Q. Going to page 10, at the bottom there's a statement that you make that says, "Although as yet unpublished, our outcomes today have been favorable. The overwhelming majority of such patients have expressed extreme satisfaction with their experience, and not infrequently the results have been enthusiastically described as life-changing." Do you see that?

A. I do.

Q. Why is your data unpublished?

A. Because it's unpublished. But it's unpublished because of time constraints and because, as a solo practitioner managing my own practice, doing my own cases, doing all the work of a practice, that amount of work, just it seems fairly daunting, but there's some medical students who are working with me that might be interested in helping do some of the legwork and get some of that done. But it really is more of a time issue than anything else. The other thing about my data is it's not a prospective type of data, so although it's, I think, interesting and it's very useful for my own patients, I'm not sure, in the big body of medical literature, where it would fall out in that pyramid of hierarchy of literature.

(*Id.* at 199:22 – 200:22).

This testimony demonstrates the unreliability of any opinions based on Dr. Schlafstein's personal experience. Dr. Schlafstein is asserting and relying on vague alleged safety and efficacy data from his own practice that he has not even tried to publish because doing so would be "daunting." Further, he admits that he would need to actually review the charts of the patients to track the product used. Dr. Schlafstein has no data regarding the number of transvaginal mesh implants he performs, the reasons for any removal of mesh products, the number of removals for various products, or the percentage of the patients in whom he has implanted transvaginal mesh products who are lost to follow up (i.e., who go to another doctor for removal). As such, his opinions about complications in his own practice are unreliable, and Plaintiffs have no reasonable way of testing the veracity of Dr. Schlafstein's claims, which exist only in his mind. Because there is no foundation for this testimony, Dr. Schlafstein should be prohibited from providing this testimony. Allowing him to do so would be akin to permitting an improper opinion about his personal complication rates.

III. Dr. Schlafstein admits that he has no expertise in the area of warnings and IFUs, and his opinions on those issues should be excluded.

As discussed in Section I, above, this Court has recognized the importance of an expert's admission that he is not an expert in the area of warnings. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d

589, 611 (S.D.W. Va. 2013), *amended on reconsideration in part* (June 14, 2013). Just like his design opinions, Dr. Schlafstein's opinions concerning the adequacy of the warnings and IFUs for the subject product should be excluded because he admits he is not an expert:

Q. You're not an expert on warnings; correct?

A. In terms of calling me an expert, in the context of how I use these products and how I warn patients, I think I am actually an expert in giving warnings to patients. So if that's what you mean, yes, but it may not be what you mean.

Q. What risk information are medical device companies required to put in the IFU?

A. These are -- those are requirements that are between them and the regulatory agencies.

Q. And you wouldn't be an expert on those requirements; correct?

A. No.

(Schlafstein Deposition, Ex. D, at 210:23 – 211:11).

Q. What was the reasoning behind putting specifics in the 2015 IFU?

A. I'm not a part of that discussion.

(*Id.* at 196:12-14).

Dr. Schlafstein has clearly admitted he is unqualified to give opinions on the adequacy of Defendants' warnings and IFUs, and has failed to do the proper research necessary to give those opinions. Based on this, Dr. Schlafstein's opinions on this issue should be precluded.

IV. Dr. Schlafstein did not seek information that potentially contradicted his own opinions, so he did not engage in a scientific process.

A final reason to exclude all of Dr. Schlafstein's opinions is that he acknowledged that his report was written as a defense of his positions, not as a scientific study. In other words, he was only looking for information that would support the opinions that he planned to give. An

example of this fact is demonstrated by his testimony about the inclusion of certain statements from societies that support the mesh industry:

Q. Are there societies that have spoken out against the use of mesh?

A. I think there are, yeah.

Q. Have you cited any of those in your report?

A. No.

Q. Why is that?

A. I'm citing -- I'm presenting my own opinions, and this is -- this is -- I didn't think it was appropriate. I didn't see any reason to.

Q. These are -- this is evidence that you're citing that you believe supports your opinion; correct?

A. Right, correct.

Q. But there's no citation of the evidence that doesn't support your opinion; right?

A. I'm not necessarily aware of what specific societies have come out against the TVT, so, no, I'm not aware of any in particular that have come out against it, so there wouldn't be any reason to include that.

(Schlafstein Deposition, Ex. D, at 164:12-165:5). Initially, he acknowledged that some societies have made statements against mesh. Yet, he could not identify what they were, because he made no effort to even determine what those groups were saying.

CONCLUSION

Based on the foregoing, Dr. Schlafstein should be precluded from giving opinions on (1) the design of Defendants' transvaginal mesh products at issue, including the safety and efficacy of those devices; (2) his statements about the safety and efficacy of Defendants' products based on his own practice; and (3) the adequacy of Defendants' product warnings and IFUs.

Dated: April 21, 2016

Respectfully submitted,

/s/ Thomas P. Cartmell

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 21, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/Thomas P. Cartmell

Attorney for Plaintiffs